

# **EXHIBIT E**

Confidential - Subject to Protective Order

1                   IN THE UNITED STATES DISTRICT COURT  
2                   FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
3                   CHARLESTON DIVISION

4                   - - -  
5    IN RE: ETHICON, INC. PELVIC :MDL NO. 2327  
6                   REPAIR SYSTEM, PRODUCTS :  
7                   LIABILITY LITIGATION :VOLUME II  
8                   :  
9

10                  - - -  
11                  THIS DOCUMENT RELATES TO ALL CASES AND  
12                  VARIOUS OTHER CROSS-NOTICED ACTIONS  
13                  CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER  
14                  - - -

15                  January 8, 2014  
16                  - - -

17                  Transcript of the continued deposition of  
18                  THOMAS A. BARBOLT, Ph.D., called for Videotaped  
19                  Examination in the above-captioned matter, said  
20                  deposition taken pursuant to Superior Court Rules of  
21                  Practice and Procedure by and before Michelle L.  
22                  Gray, a Certified Court Reporter, Registered  
23                  Professional Reporter, and Notary Public, at the  
24                  offices of Riker Danzig Scherer Hyland & Perretti  
25                  LLP, Headquarters Plaza, One Speedwell Avenue,  
                      Morristown, New Jersey, commencing at 9:07 a.m.

26                  - - -  
27                  GOLKOW TECHNOLOGIES, INC.

28                  877.370.3377 ph | 917.951.5672 fax

29                  deps@golkow.com

Confidential - Subject to Protective Order

1 after ten years revealed no changes in material.

2 That's not actually true, is it?

3 MR. THOMAS: Object to the form of

4 the question; scope.

5 BY MR. THORNBURGH:

6 Q. That statement that Ethicon had  
7 previously implanted Prolene suture into dogs, and  
8 explants after ten years revealed no changes in the  
9 material, is not a true statement, is it?

10 MR. THOMAS: Object to form; scope.

11 THE WITNESS: There were three  
12 elements, three important elements in that study.

13 The key elements, as we've discussed  
14 earlier, were molecular weight and tensile strength.  
15 And in that seven-year dog study, which -- which is  
16 referenced as ten year here, there was no impact on  
17 molecular weight, nor tensile strength.

18 BY MR. THORNBURGH:

19 Q. There was surface cracks observed on  
20 the surface layer of the polypropylene in that  
21 study, correct?

22 A. Surface changes were observed in some  
23 of the fibers in some of the dogs.

24 Q. Are you telling the ladies and  
25 gentlemen of the jury that when the outer surface of

Confidential - Subject to Protective Order

1 the polypropylene fibers crack and peel away from  
2 the surface, that that is not degradation?

3 MR. THOMAS: Object to the form of  
4 the question.

5 THE WITNESS: I am telling listeners  
6 that the key endpoint of adverse effects of  
7 degradation are molecular weight and tensile  
8 strength, both quantitative measures, not subjective  
9 assessments of surface changes, but quantitative  
10 measures that hold great weight and suggest that  
11 there's no degradation to the Prolene fiber in terms  
12 that are significant.

13 BY MR. THORNBURGH:

14 Q. Do you agree there's been studies  
15 conducted that show that when the polypropylene  
16 fiber surface or lose -- or fragments come off of  
17 the polypropylene surface as a result of  
18 degradation, that that increases the inflammatory  
19 response?

20 MR. THOMAS: Object to the form of  
21 the question.

22 BY MR. THORNBURGH:

23 Q. You've seen those studies, haven't  
24 you?

25 MR. THOMAS: Object to the form of

Confidential - Subject to Protective Order

1 MR. THOMAS: Object to the form of  
2 the question; scope.

3 THE WITNESS: 2007?

4 BY MR. THORNBURGH:

5 Q. I'm sorry. October 29, 1997.

6 Correct?

7 A. Okay. That would be the time of the  
8 submission of the 510(k) for TVT original or  
9 retropubic.

10 Q. Right. So October 29, 1997 Ethicon  
11 submitted to the FDA the 510(k) submission related  
12 to the TVT-Retropubic, correct?

13 A. Yes.

14 Q. And in that submission, Ethicon  
15 stated that the material is not absorbed, nor is it  
16 subject to degradation.

17 Do you see that?

18 A. Yes.

19 Q. But as we've already established, by  
20 1990 and 1992, Ethicon was aware from its own  
21 internal studies that the Prolene in the TVT was  
22 subject to surface degradation, correct?

23 MR. THOMAS: Object to the form of  
24 the question.

25 THE WITNESS: We've talked a lot

Confidential - Subject to Protective Order

1 about this before.

2 BY MR. THORNBURGH:

3 Q. Correct?

4 A. And as I indicated before, there were  
5 three endpoints in that experiment that are  
6 important: Subjective observations, observations by  
7 a human being about what's on the surface of the  
8 suture, and then quantitative assessments of  
9 molecular weight, and quantitative assessments of  
10 tensile strength.

11 In terms of surface changes, surface  
12 changes were reported. In terms of molecular weight  
13 and tensile strength, no impact on either of those  
14 parameters, which would lead one to conclude that  
15 there's no evidence of degradation that's  
16 meaningful.

17 MR. THORNBURGH: Move to strike;  
18 nonresponsive.

19 BY MR. THORNBURGH:

20 Q. Sir, do you think it's okay for  
21 Ethicon to misrepresent information in a 510(k)  
22 submission to the FDA regarding surface cracking?

23 MR. THOMAS: Object to the form of  
24 the question.

25 THE WITNESS: I don't think they've

Confidential - Subject to Protective Order

1

2 CERTIFICATE

3

4

5 I HEREBY CERTIFY that the witness was  
6 duly sworn by me and that the deposition is a true  
7 record of the testimony given by the witness.

8

9 It was requested before completion of  
10 the deposition that the witness, THOMAS A. BARBOLT,  
11 Ph.D., have the opportunity to read and sign the  
12 deposition transcript.

13

14

15

16

---

17 MICHELLE L. GRAY, a Registered  
18 Professional Reporter, Certified  
19 Shorthand Reporter and Notary Public

Dated: January 16, 2014

20

21

(The foregoing certification of this  
22 transcript does not apply to any reproduction of the  
23 same by any means, unless under the direct control  
24 and/or supervision of the certifying reporter.)

25